University of Fort Hare
Together in Excellence

HEALTH RESEARCH ETHICS COMMITTEE

STANDARD OPERATING PROCEDURE FOR THE ESTABLISHMENT OF STANDARD OPERATING PROCEDURES

1. DOCUMENT HISTORY

Date	Version No	Reason for revision
11 July 2018	1	Newly formulated
31 January 2022	2	Updated

2. PURPOSE

To provide a framework for all standard operating procedures (SOPs) for the UFH HREC pertaining to documentation, procedures, and processes to ensure standard and uniform practices.

3. SCOPE

The document covers the establishment of all new SOPs, responsibilities, and procedure(s), the essential elements to be included, and a template to establish an SOP for the UFH HREC.

4. RESPONSIBILITIES

The Chairperson, Vice-chairperson, and Ethics Administrator should be aware of the procedure to establish an SOP for UFH HREC to ensure a standardised approach.

5. PROCEDURE(S)

- Should the need arise to establish a new SOP for the UFH HREC, a request must be submitted to the HREC.
- The UFH HREC will review the request and authorise/decline the establishment of the SOP.
- The outcome of the decision of will be communicated to the requestor through email.
- On receipt of approval, the requestor will then write the SOP according to SOP_UFH HREC_1.1: SOP to establish SOPs and use the provided template.
- SOPs are numbered using the prefix:
  - For SOPs for the UFH HREC - SOP_UFH HREC_1.1
- The first SOP draft must be sent electronically to the UFH HREC, and the version number of this draft is indicated as Draft 1.
- The SOP will be distributed to the UFH HREC.

- Any changes in the SOP will be sent to the Chairperson to implement with the requestor.
- The SOP is finalised, approved and signed by all parties.
- The SOPs for general use and the RECs on the UFH HREC Ethics Webpage, and a notice sent to all UFH HREC members and staff.
- The UFH HREC will place the SOP on the Webpage of the Ethics Office after approval.
- The UFH HREC administrator keeps a database of all SOPs.
- SOPs are revised as indicated on the specific SOP, following the same process during its development.
- SOPs must be strictly adhered to, and if an SOP becomes redundant, it should be withdrawn and widely communicated.

6 ESSENTIAL ELEMENTS TO BE INCLUDED IN A SOP
- Title of the SOP and number
- Document history
- Purpose of the SOP
- Scope
- Abbreviations and/or definitions
- Responsibilities
- Procedure(s) to be followed
- Reference documents
- Addenda
- Any other elements essential to the specific SOP

7. REFERENCE DOCUMENTS

- University of South Africa, SOP for SOPs
- North -West University, SOP for SOPs